

REMARKS

Claims 21-43 are pending as of the Office Action of March 3, 2008. In this Office Action the Examiner requires Applicant to elect a single Group to which the claims shall be restricted under 35 U.S.C. 121.

Particularly, the Examiner identifies:

Group I: Claims 21-27 and 30-33

Group II: Claims 28-29; and

Group III: Claims 34-43.

The Examiner further requires Applicant to elect a Species from the radionuclides and Chelating Agents (see page 3 of the Office Action) if any of the above Groups are elected, or a Species from the Cancers (also on page 3 of the Office Action) if Group III is elected.

In reply to the restriction requirement, Applicants herein elect Group I, Claims 21-27 and 30-33, and the Bi-213 species (which reads at least on claims 21-23, 25-27, and 30-33) **with traverse**. Despite the Examiner's allegations to the contrary, Applicant respectfully traverses on the grounds that a radioimmunoconjugate comprising an alpha-emitting radionuclide bound to a monoclonal antibody, C595 (as recited in claim 21) is a special technical feature in view of Crit. Rev. Oncol. Hermatol. Vol. 39 (1-2) pages 139-146, 2001 to Allen ("Allen" hereinafter) and Br. J. Cancer Vol. 76 (5) pages 614-621, 1997 to Denton ("Denton" hereinafter).

More specifically, Applicant respectfully asserts that neither Allen nor Denton, taken alone or in combination, teach usage of C595 in **radio**-immunotherapy (as is recited in Applicant's claim 21), especially in a radioconjugate where it is bound to an **alpha-emitter**. Instead, Allen discloses the general concept of alpha therapy, and Denton mentions **potential application** of the antibody scFv (not the native, parent antibody C595) as an immunotherapeutic agent, and certainly does not teach an arming of scFv with radioisotopes or toxins. Accordingly, any proposed combination of Allen and Denton does not teach a **radioimmunoconjugate** comprising an alpha-emitting **radionuclide** bound to a monoclonal antibody, C595, and thus, for

at least this reason, Applicant respectfully submits that Applicant's claim 21 includes a special technical feature.

Furthermore, Applicant respectfully and preemptively points out that any possible usage of Perkins et al. (disclosed in the International Search Report) to similarly render Applicant's claim 21 obvious would be improper. Though Perkins describes usage of conjugates of C595 with a beta-emitter in bladder cancer, an exemplary embodiment of Applicant's disclosure relates to cancer therapy and more specifically to a treatment modality called alpha-radioimmunotherapy (alpha-RIT). An exemplary embodiment of Applicant's disclosure demonstrates that radioconjugates (RIC) of an alpha-emitter with the monoclonal antibody C595 can be efficiently used in cancer therapy, and is particularly efficient for treating breast, prostate, ovarian and pancreatic cancers. It was not possible to predict this therapeutic efficacy from the experiments on bladder cancer with beta-emitters conjugated with C595, as taught in Perkins.

Applicant notes that one important issue of radio-immunotherapy is to find and produce conjugates that are therapeutically effective in one or more diseases. However, the design of a radioimmunoconjugate is a complex task. RIC design depends mainly on: (1) availability of a Mab of high affinity and specificity; (2) a suitable radionuclide with desired physical properties; (3) and appropriate chelating agent (linker).

It is also essential to note that alpha and beta radioimmunotherapy are two **different worlds**. Experts in the field of alpha-RIT are not experts in beta-RIT. The specificities are so different that Physicians (Doctors) and Researchers specialize and practice only in one of these medical/therapeutic fields. Still further, as illustrated by the literature, in some cases beta-RIT may be more appropriate, and in other cases alpha-RIT is preferable.

Lastly, the *Seyed* reference (XP002206123) cited in the International Search Report indicates that: "*The pharmacokinetics of short-lived alpha-particles **cannot be extrapolated from that of the regularly used I-131 or any other long-lived beta-emitter where it is dominated by biologic clearance of the antibody***". Hence, Applicant respectfully asserts that the cited prior art

does **not** contain any *motivation* to build the claimed RIC, nor does the prior art provide any any *expectation of success*, as it was not foreseeable that the claimed RIC would be stable and provide therapeutic efficiency. Therefore, the present invention is not obvious over any of the above discussed prior art.

Provided the above discussed traversal is ineffective, Applicants respectfully reserve the right to pursue the withdrawn claims in a related application(s) without prejudice.

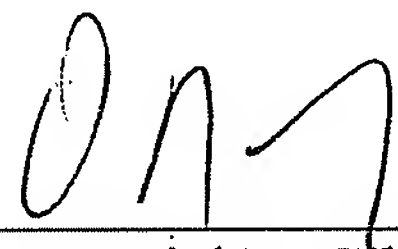
Prosecution on the merits is respectfully requested. The foregoing is believed to be fully responsive to the outstanding Office Action.

The Examiner is invited to contact Applicant's attorney at the below-listed phone number regarding this Response or otherwise concerning the present application.

Applicant hereby petitions for any extensions of time necessary under 37 C.F.R. §§1.136(a) or 1.136(b).

If there are any charges due with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Applicant's attorneys.

Respectfully submitted,
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